Nazir Khan and
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Plaintiff

v.

1.Hemosphere Inc.
2.Cryolife Inc.
3.Merit Medical Systems Inc
4. Hospitals and doctors implanting unpatented HeRO graft to Doctors

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United States District Court Northern District of Illinois, Eastern Division

Civil Action Number

1:18-cv-05368
Judge Andrea R. Wood
Magistrate Judge Maria Valdez

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CLERK, U.S DISTRICT COURT

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)

Defendants)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Nazir Khan MD and Iftikhar Khan MD. complains of Hemosphere Inc, 6545 City West Parkway, Eden Prairie, MN 55344. Cryolife Inc., 1655 Roberts Blvd., NW, Kennesaw, GA 30144, and Merit Medical Systems, Inc 1600 West Merit Parkway South Jordan UT 84095 and listed doctors and hospitals as follows.

NATURE OF THE ACTION

1. This is a patent infringement action to stop the Defendant's infringement of Plaintiffs, Nazir Khan MD's and Iftikhar Khan MD's patent titled, " Khan Hybrid Arteriovenous Shunt" US patent No. 8747344B2, issued 6/10/2014, by the following companies; Hemosphere Inc, 6545 City West Parkway, Eden Prairie, MN 55344. Cryolife Inc., 1655 Roberts Blvd., NW, Kennesaw, GA 30144, and Merit Medical Systems, Inc 1600 West Merit Parkway South Jordan UT 84095 and listed doctors and hospitals above implanting into patients, the infringing device, the HeRO® Graft.
   The Plaintiffs are in possession of the written description of patent number US 8747344B2 filed on Mar 29, 2004 (hereinafter, the "344 Patent" or the "Patent-in-suit") A copy of the Patent-in-suit is attached hereto as Exhibit C The Plaintiffs seek monetary damages.

THE PARTIES

2. Plaintiffs, Nazir Khan MD and Iftikhar Khan MD, are licensed physicians and surgeons in Illinois and are the exclusive licensees of the Patent-in-suit and possess all rights thereto, including the exclusive right to exclude

the Defendents from making, using selling, offering to sell, implanting in patients, or importing in this district and elsewhere into the United States and territories the patented invention(s) of the Patent-in-suit, the right to sublicense the Patent-in-suit, and to sue the Defendents for infringements and to recover past damages.

3. Hemosphere Inc, is a company organized under the laws of Minnesota , with its principal place of business at 6545 City West Parkway, Eden Prairie, MN 55344. Cryolife Inc., is a company organized under the laws of Georgia, with its principal place of business at 1655 Roberts Blvd., NW, Kennesaw, GA 30144. Merit Medical Systems, is a company organized under the laws of Utah, with its principal place of business at Inc 1600 West Merit Parkway South Jordan UT 84095. The above listed doctors and hospitals listed above, implanting into patients, the infringing device, the HeRO® Graft are listed at their addresses in their respective states.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the Patent Laws
of the United States, Title 35 of the United States Code.
5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over the Defendants because among other things they transact business in this district, at least by offering to sell, selling, implanting the HeRO Graft into patients and/or advertising product device(s) such as the HeRO® Graft in such a way as to reach consumers and doctors/hospitals in Illinois and in this judicial district including, but not limited to, over the internet, radio, television, and through local doctors offices and hospitals located throughout this district. The Defendant(s) also directly market and sell the infringing product(s) and services through their website https://www.merit.com/peripheral-intervention/access/renal-therapies-accessories/merit-hero-graft/patients/find-a-physician/ , whereby patients and doctors/hospitals can learn about implantation of the infringing HeRO Graft.
7. Defendant(s) have, consequently, committed acts of infringement in this judicial district.

COUNT 1:INFRINGEMENT OF PATENT 344

8. The plaintiffs reallege and incorporate by reference the above paragraphs of this Complaint, inclusive, as though fully set forth herein

Patent 344 is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code. The Defendants have infringed and continue to infringe upon Patent 344, claim 13 under Title 35 of USC, 112, para 6.

Background of Invention:

A Hybrid arteriovenous shunt that serves as a conduit connecting an artery to the right atrium of the heart whereby the impure arterial blood flows continuously to the right atrium (see Fig. 1 in Exhibit A)

The claimed invention has three parts (see Fig. 1 of Patent 344 and Fig. 1 of Exhibit A); the arterial graft, cuff connector, and a venous outflow catheter configured for insertion through the vein into right atrium of the heart. In a conventional Arteriovenous shunt, the arterial graft is connected to the artery and to the vein by surgical anastomosis. In this arteriovenous shunt (see Fig IV) where the graft is connected to the artery and to the vein by anastomosis. Because the arterial blood flow pressure is very high, the vein wall, which is used to very low blood pressure becomes damaged resulting in neo-intimal hyperplasia. This results commonly in failure of the arteriovenous shunt

in 80% of cases (see Fig 4 and Patent 344 Specification column 5 line 60-65). This problem was solved by Patent 344 by connecting an arterial graft to the venous outflow catheter so that the blood is directly guided into the right atrium of the heart and no blood comes into contact with the vein, thereby eliminating the 80% shunt failure rate. The structure of the Patent 344 as described in Fig. 1 and Fig 2, and the patent Specification column 2, line 21-45, describe the three parts of the claimed device. In Fig.1 of Patent 344, the three parts of the arteriovenous shunt (No.10), are connected via the cuff connector which is disposed about the venous outflow catheter and the graft. Exhibit B, Fig 1 demonstrates that the HeRO graft has 3 main components; 1. The He®RO Graft Component, 2. The titanium connector 3. The He®RO outflow component. The titanium connector connects the He®RO Graft component and the Hero outflow component and is disposed within the lumen of both, see Exhibit B, Fig3 Patent 344 is equivalent to the accused He®RO Graft. The difference is the disposition of the connector. This change of the disposition of the connector is insubstantial, because the function is identical with the diversion of the blood from the arterial graft to the venous outflow component (catheter). Therefore, the structure of Patent 344 is equivalent to the accused He®RO Graft device.

9. **Literal infringement of Patent 344, claim 13 under 35 USC 112, para 6.**

The statute states, "An element in a claim for a combination may be expressed as a…means or step for performing a specified function without a recital of structure, material or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

In Patent 344, claim 13, the structure is a means for performing hemodialysis, meaning the removal from impure arterial blood of toxins and the purified blood is returned to the patients of chronic renal failure. The means function is disclosed in the method process of the specification of the Patent 344, column 5 , line 45-65 and column 6 line 5-14. The structure that performs the means function is found in the specification under the written description in Fig 1 no10 , Fig.2 and Fig. 3. Col 2 line20-35 line 36-65 col429-55. Also, the means function is found in the method process, of specifications patent 344 at column 5 line 45-65 and column 6 line 5-14. In the claimed invention, Patent 344, performs the function of dialyzing(cleaning) the impure blood in chronic renal failure. The blood is taken from the arterial graft to the dialysis machine via a dialysis cannula and then returned to the arterial graft via a dialysis cannula. From the arterial graft, the dialyzed (cleaned) blood, is then is directed via a cuff

connector into the venous outflow catheter, whereby it is deposited into the right atrium of the heart. The cuff connector is disposed about the arterial graft and venous outflow catheter. The equivalent structure of the claimed device as described in the specifications performs the identical function of the infringing HeRO® graft. The method of dialysis of the HeRO graft is identical to the claimed device. The blood is in the HeRO Graft from the arterial graft to the dialysis machine via a dialysis cannula and then returned to the arterial graft via a dialysis cannula. See Odetics Inc v. Storage Tech. Corp., 185 F,3d1259,1267,51 USPQ 2d1225,1229(Fed Cir.1999); See Penwalt Corp v. Durand-Wayland, Inc 833 F 2d 931, 934,4 USPQ 2d 1737,1739(Fed.Cir, 1987) (en banc). The dialysis the performed the same way in the both the devices. See Chiuminatta, 145 F 3d at 1308, 46USPQ2d at 1755-56. Therefore, the accused device, literally infringes upon claim 13 of Patent 344 under 35USC 112, para 6.

10. Contributory infringement, under 35 USC 271 (c), of the venous outflow catheter of Patent 344 occurs because of the following. The HeRO ®Graft, manufactured by the Hemosphere Inc., uses in their device, a venous outflow catheter which is identical to our catheter, represented by no 12 of patent 344. In their original patents (US patent 6,582,409 B1 issued 06/24/2003 assigned to GraftCath(later called

Hemosphere, Inc), and US Patent US RE44,639 E ,reissued 12/10/2013), their catheter are supposed to be inserted into the vein only see Exhibit A Fig. II, and not into the right atrium of the heart, as is clear in the wording of these two patents. Our device has patent protection on insertion into the right atrium of the heart, see Fig. 1 No. 12 of Patent 344. Thereby, GraftCath(later called Hemosphere), Hemosphere Inc, Cryolife, and Merritt Medical systems which produced or now produce the "HeRO ®Graft" are infringing on our patent, the "Khan Hybrid Arteriovenous Shunt". Hemosphere Inc. manufactured and sold the HeRO Graft from 2008 until May15, 2012 when Cryolife acquired and integrated Hemosphere Inc. Cryolife then manufactured and sold the HeRo graft until they sold the "HeRO ®Graft" and related assets to Merit Medical Systems Inc, on Feb 4, 2016. Since Feb 4, 2016, Merit Medical Systems Inc., has be manufacturing and selling the "HeRO® Graft". In Patent 344, see Fig.2 and Fig.3, the venous outflow catheter represented by number 12 in Fig.1 is connected by a cuff connector, number 13, to the graft number 11, as shown in the specification col. 2 line21-45 and col.4 line 46-54. the venous outflow catheter is then configured for insertion through the vein into the right atrium. In the accused device, the HeRO® Graft, the companies mentioned, sell the venous outflow catheter as a separate part in the construction of the

HeRO ®Graft device, and therefore infringes on Patent 344 under 35 USC 271 (c).

11. The three aforementioned companies made the invention, Patent 344, without permission and violated 35 USC 271(a). Hemosphere Inc. demonstrated induced infringement of Patent344, by selling our patented device in the form of the HeRO® Graft to Cryolife. Cryolife is guilty of induced infringement on Patent 344, by selling our patented device in the form of the HeRO® Graft to Merit Medical Systems, Inc under 35 USC 271(b). Merit Medical Systems is also liable for induced infringement upon Patent 344, under 35 USC 271 (b) because it sold the device to hospitals and advertised on the internet via their website.
12. All doctors named as defendants, in various hospitals and clinics, are making the HeRO ®Graft from the components supplied by the three aforementioned companies and are implanting the HeRO ®Graft in patients without our per mission. Therefore, they are infringing upon Patent 344, under 35 USC 271 (a).

13. Hemosphere Inc, Cryolife Inc., and Merit Medical Systems Inc., all demonstrated willful infringement upon Patent 344. Our patent, explicitly states, that the

venous outflow catheter is positioned into the right atrium of the heart so that the purified blood is deposited into the right atrium after dialysis. The HeRO ®Graft is required under Patent 6,582,409 assigned to Hemosphere Inc., and US RE44,639, assigned to Hemosphere Inc., to position their catheter into the vein so that the purified blood after dialysis is deposited into the vein (see Fig. 2 and Fig. 3 of Exhibit A), not into the right atrium of the heart. Therefore, all three companies are liable for willful infringement and trebled damages

JURY DEMAND AND INJUNCTIVE RELIEF

Under Rule 38(b) of the Federal Rules of Civil Procedure, Nazir Khan and Iftikhar Khan respectfully request a trial by jury on all issues. The petitioners also request injunctive relief, prohibiting Merit Medical Systems from manufacturing and selling of the HeRO ® Graft. The petitioners demand damages, compensatory and punitive, in excess of $1,000,000 or more.
Since 2008 the aforementioned 3 companies sold thousands of HeRO Graft devices. The owners of Patent 344, therefore deserve royalties on all sold devices starting in 2008.

Respectfully submitted,

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Exhibit A Fig 1

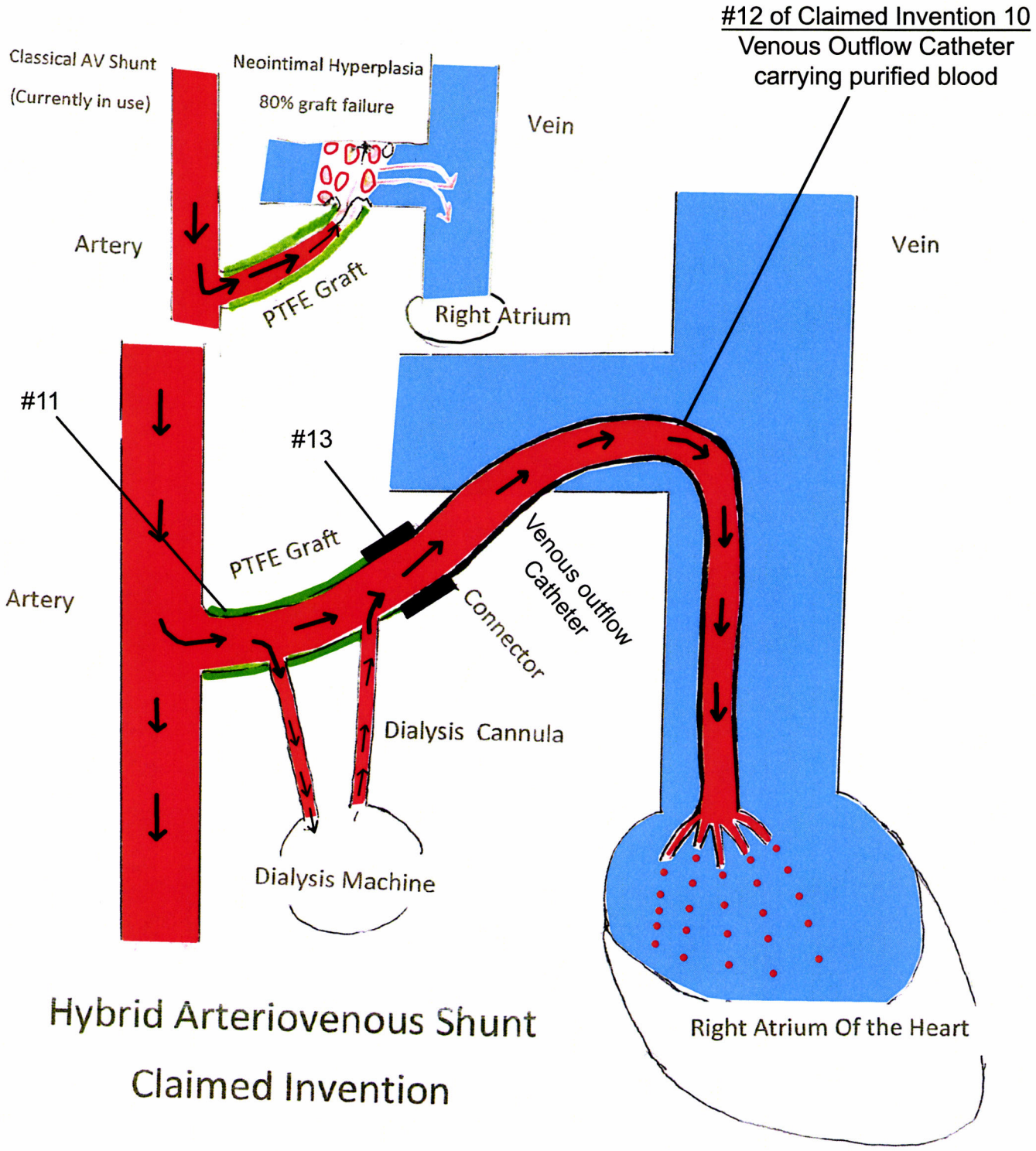
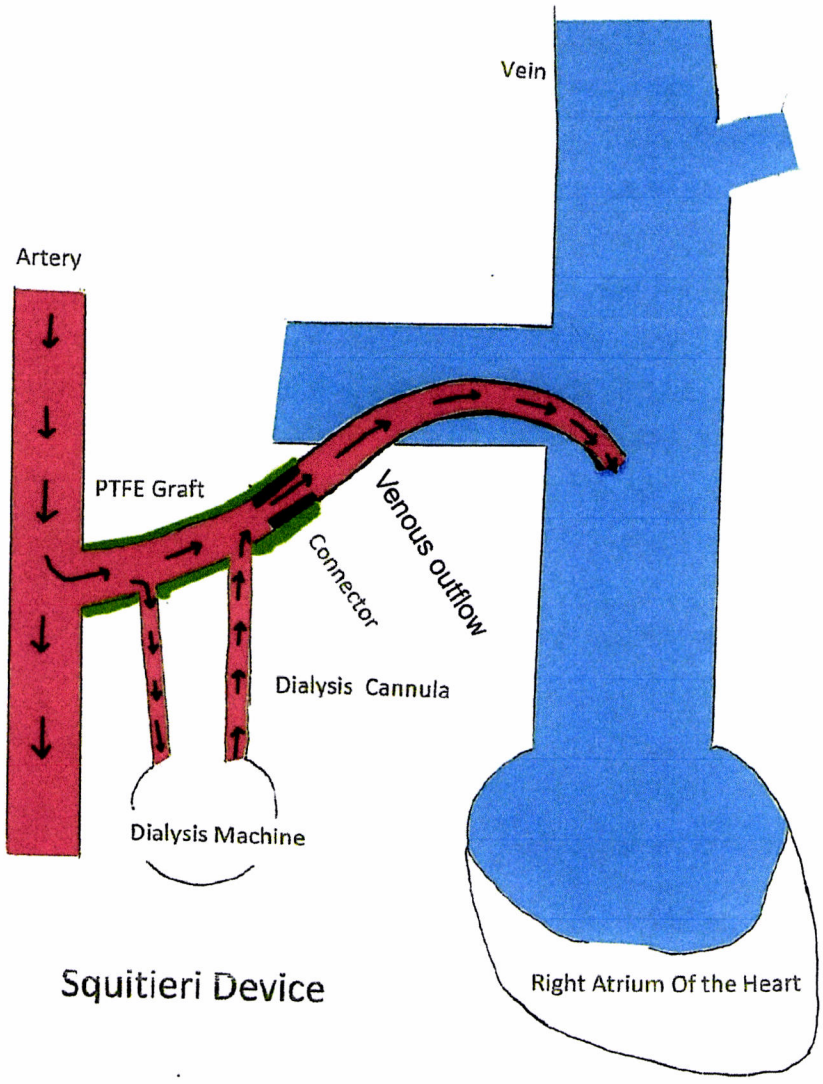


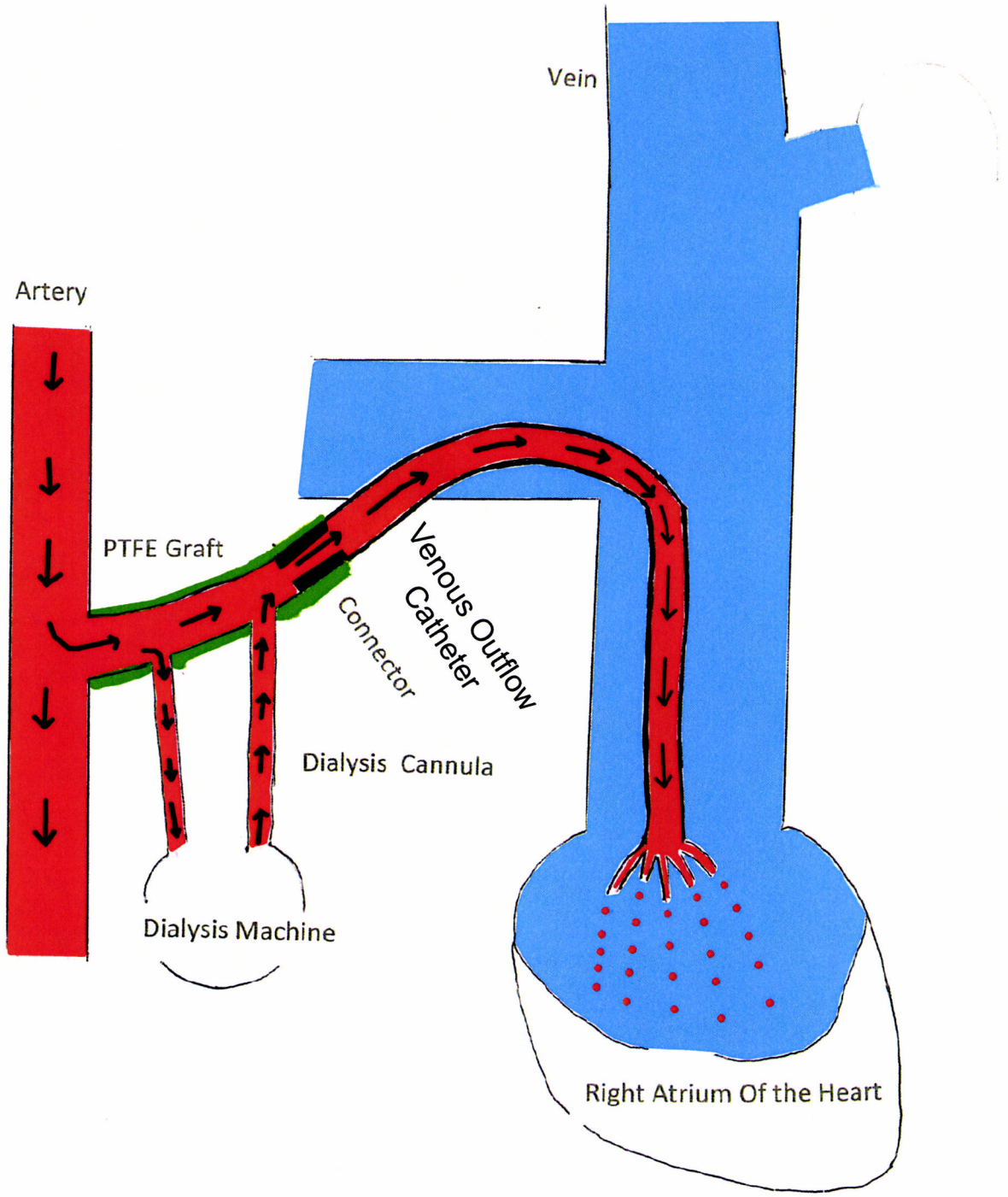
Fig I

Exhibit A Fig. 2



Squitieri Device

Exhibit A Fig 3



HeRO Vascular Access Device

Exhibit B Fig. 1

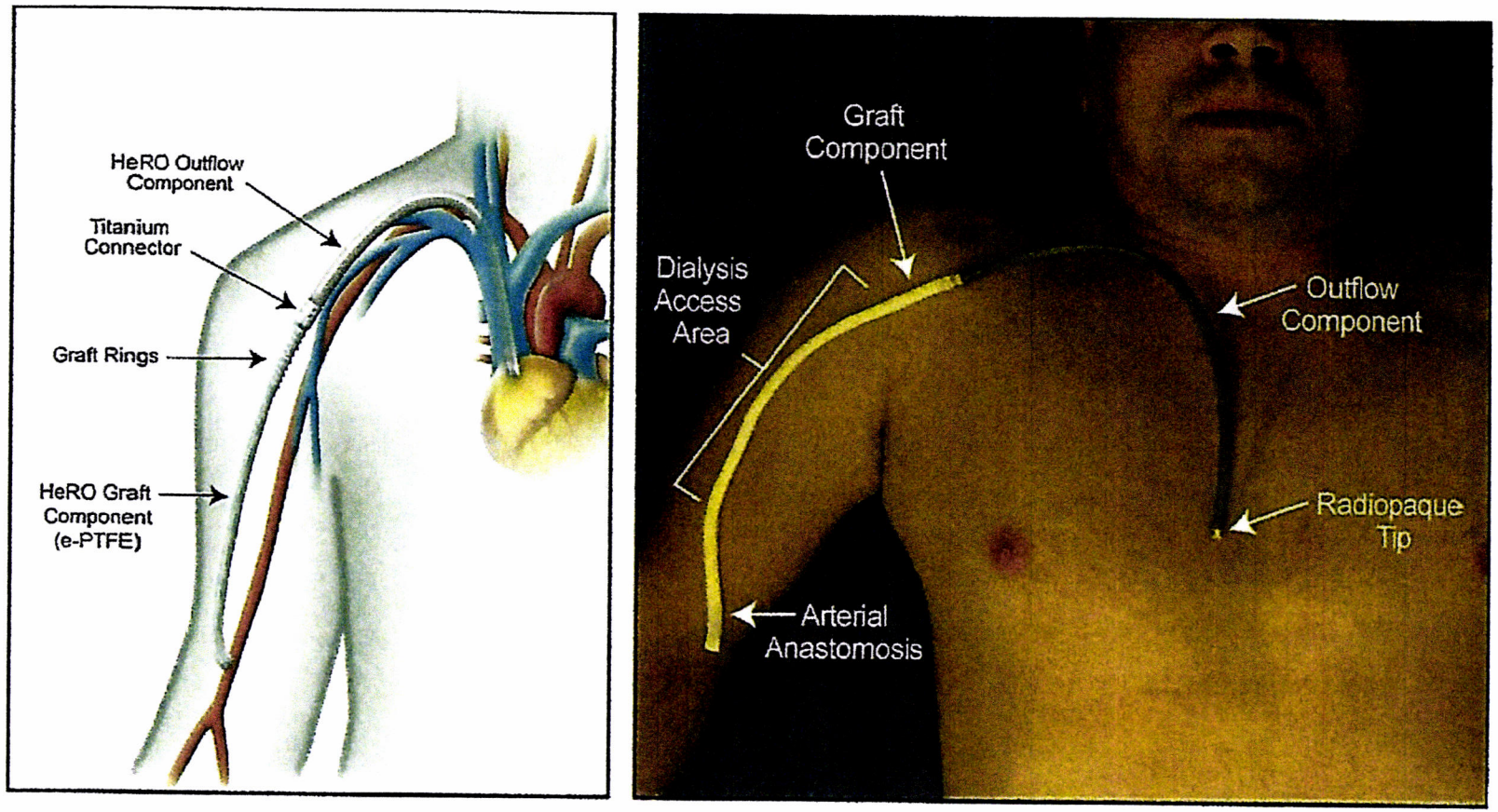


Fig 1. Hemodialysis Reliable Outflow (*HeRO*) right-sided implant. *e-PTFE,* Expanded polytetrafluoroethylene.

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Exhibit B Fig. 2

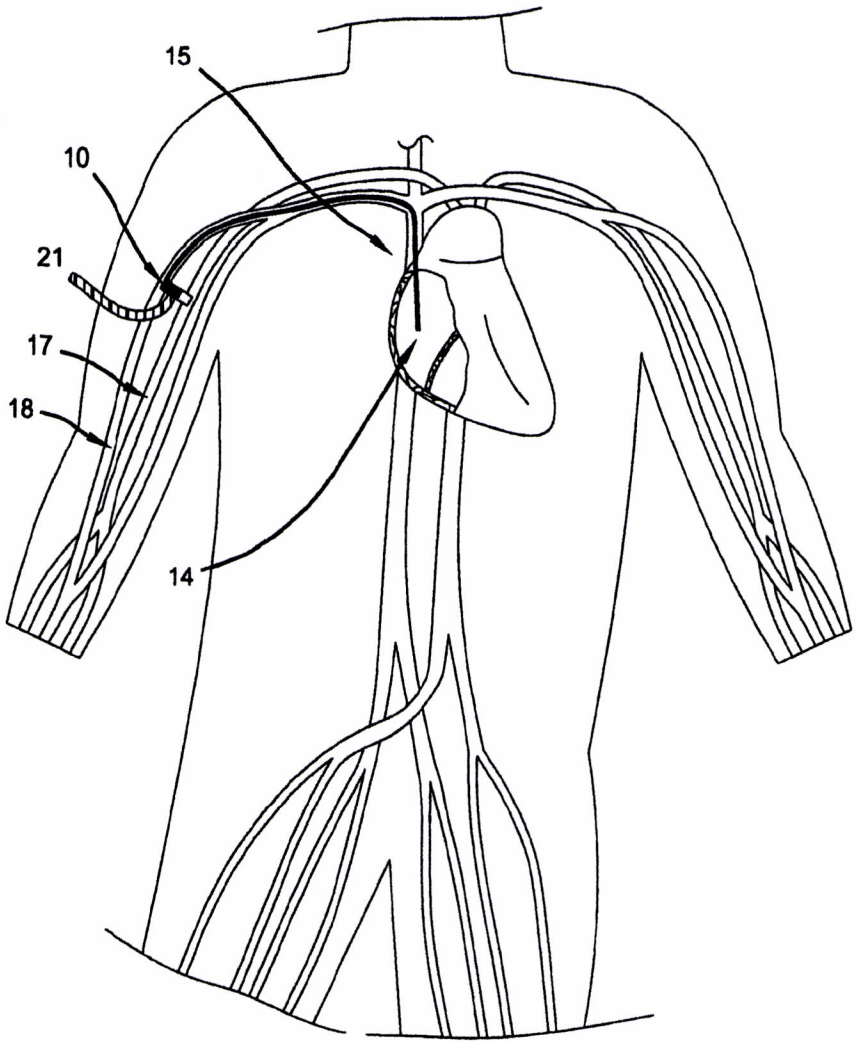

FIG 2

Exhibit B Fig. 3

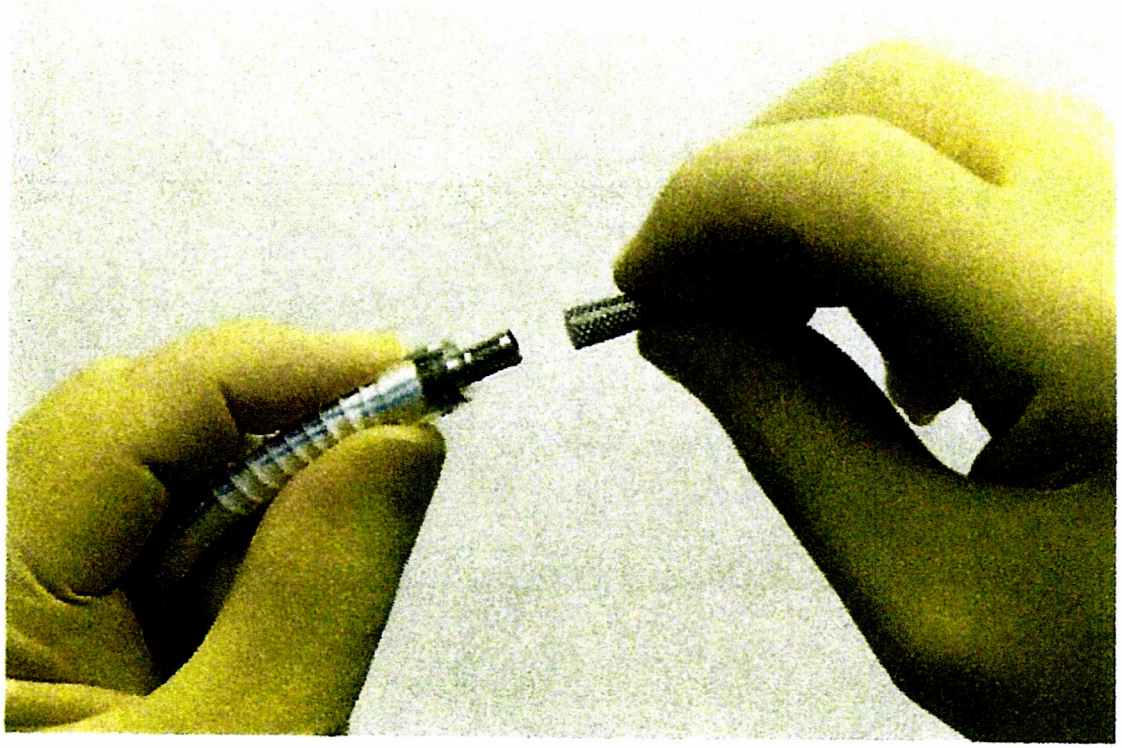

Fig 2. Hemodialysis Reliable Outflow (HeRO) graft to outflow component connection.

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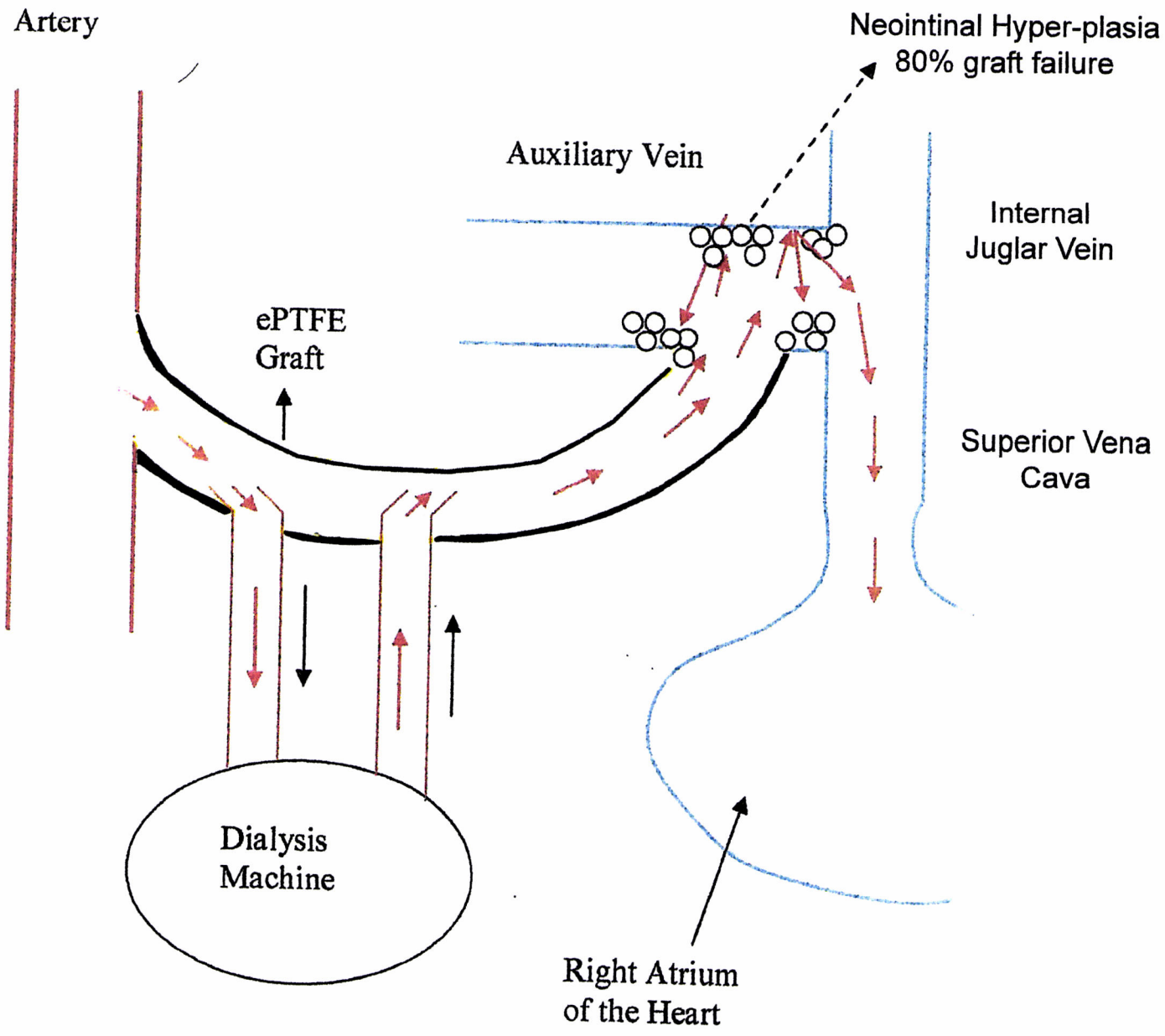

ARTERIOVENOUS SHUNT – (1976
Subcutaneous with ePTFE conduit

Fig IV

Exhibit C

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Khan

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(54) **HYBRID ARTERIOVENOUS SHUNT**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(22) Filed: **Oct. 5, 2012**

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Related U.S. Application Data

(63) Continuation of application No. 10/812,380, filed on Mar. 29, 2004, now Pat. No. 8,282,591.

(51) **Int. Cl.**
A61B 19/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/7**

(58) **Field of Classification Search**
USPC 604/7–10, 6.16, 272, 533, 264, 507–8, 604/271; 210/645, 646, 600, 634; 606/153, 606/167
See application file for complete search history.

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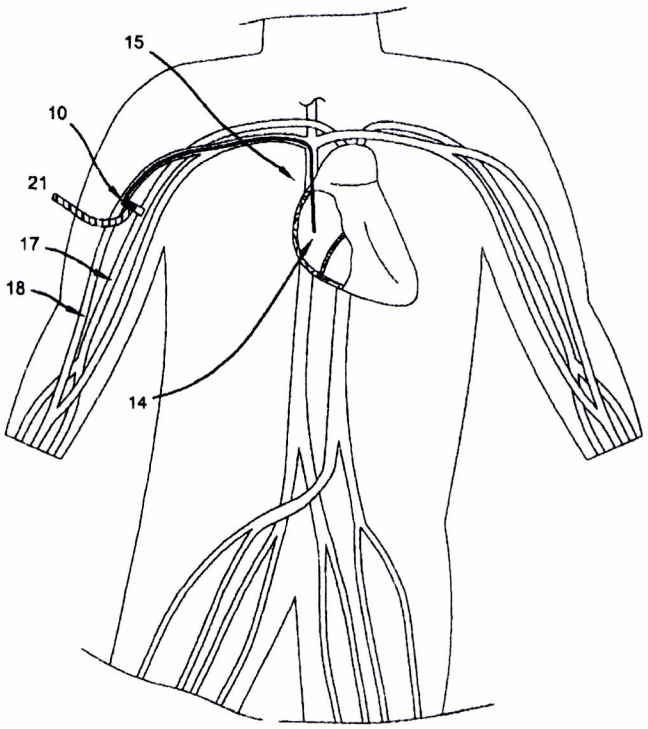
Primary Examiner — Leslie Deak

(57) **ABSTRACT**

An apparatus for positioning a graft and catheter operable for subcutaneous access to the vascular system of a patient. A surgically created, hybrid arteriovenous shunt is provided which comprises a flexible graft and a venous outflow catheter connected to the graft via surgical anastomosis over a cuff. The graft is connected to an arterial source and then to a single lumen venous outflow catheter which deposits dialyzed blood directly into the heart at the right atrium. Methods of surgical placement and performing hemodialysis using embodiments of the apparatus are provided.

20 Claims, 3 Drawing Sheets



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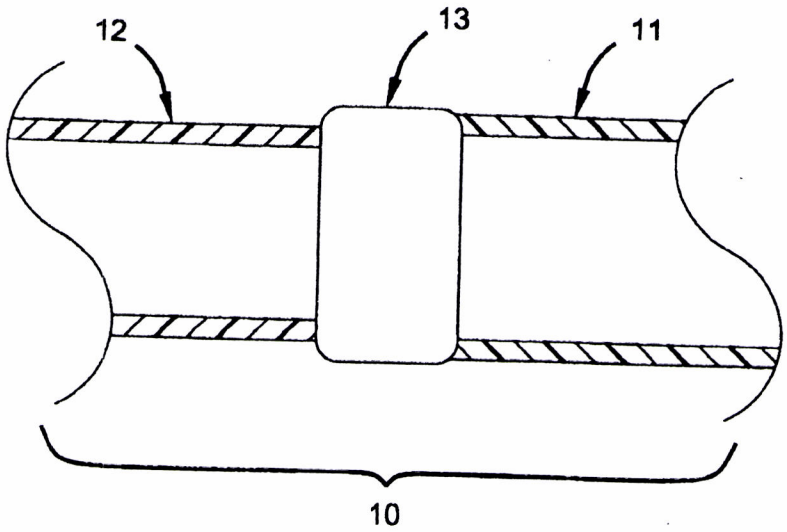

FIG 1

Exhibit C

#12 Claimed of invention 10
Venous Outflow Catheter
see Fig I

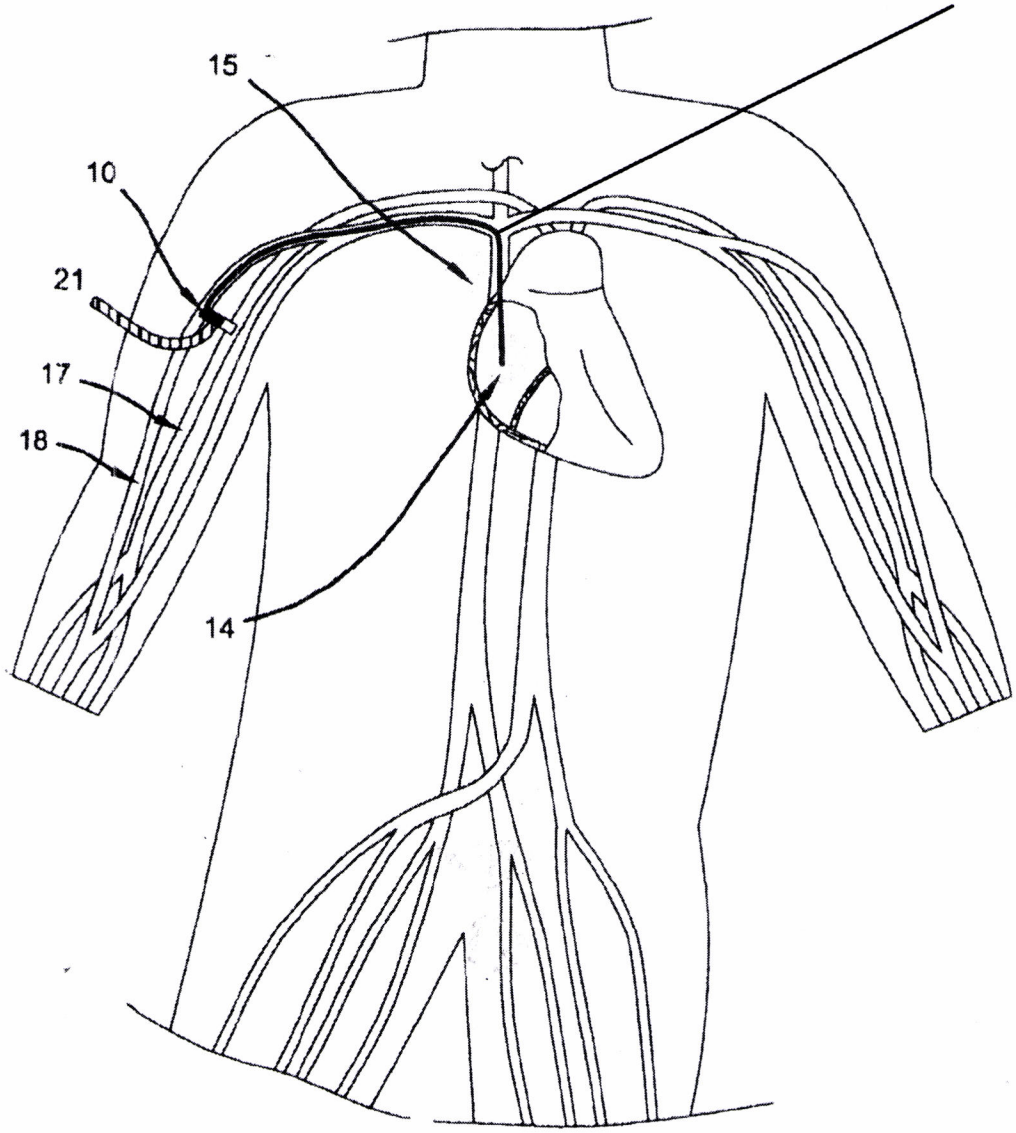

FIG 2

Exhibit C

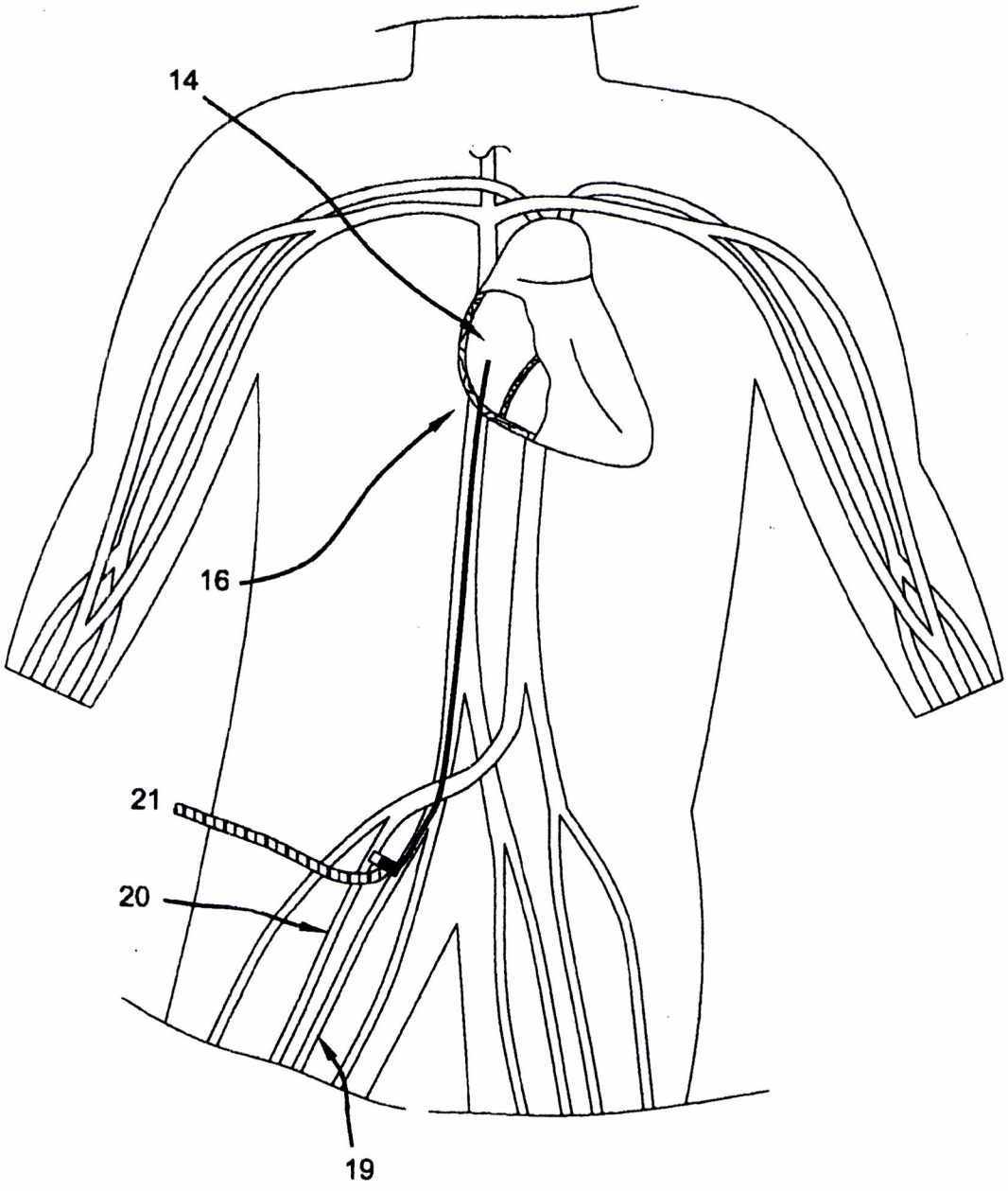

FIG 3

Exhibit C

HYBRID ARTERIOVENOUS SHUNT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 10/812,380 filed on Mar. 29, 2004 and entitled Hybrid Arteriovenous Shunt, which is hereby incorporated by reference herein in its entirety.

BACKGROUND OF THE INVENTION

Field of the Invention

Hybrid Arteriovenous Shunt

The present invention relates to devices, systems and methods for subcutaneously positioning a graft and catheter for access to the vascular system of a patient.

The present invention relates to methods and apparatus for subcutaneously positioning a graft and catheter for access to the vascular system of a patient. In particular, this invention relates to an arteriovenous (AV) shunt for use in conjunction with hemodialysis.

Hemodialysis is the purification of blood by removing toxic substances and restoring chemical balance using an extracorporeal dialysis machine. The process is used as a substitute for proper kidney function in those with renal failure. Despite the benefits, a persistent drawback of hemodialysis devices is patient morbidity and mortality caused by failure of and infection from the hemodialysis access site. In particular, nearly 80% of access failure in arteriovenous grafts is caused by blood returning from the hemodialysis machine into the patient with sufficient high pressure to damage vein walls. Morbidity and Mortality of Dialysis, NIH Consens. Statement 1993; 11:1-33.

Hemodialysis access sites include arteriovenous grafts, arteriovenous fistulas and hemodialysis catheters. An arteriovenous graft is a tube surgically placed under the skin, which is connected to an arterial source on one end and a venous source on the other. The graft is accessed by the cannulas of the dialysis machine, so the blood is removed from the body, cleansed in the dialysis filter and then returned to the patient. An AV fistula is a direct connection of an artery to a vein where a graft is not used. The vein is used for dialysis access. A hemodialysis catheter is a percutaneous tube placed through the skin and directly into the subclavian vein, internal jugular vein or femoral vein. The extracutaneous portion is used for dialysis access.

These access methods are problematic because they cause vein damage and leave the patient susceptible to infection and clotting. Furthermore, the weak veins of renal failure patients may not accommodate certain access methods.

In AV grafts, neointimal hyperplasia is caused when the cells of the inner layer of the vein hypertrophy and multiply in response to the high blood flow and pressure of the arteries. This multiplication along with turbulent flow causes frequent venous outflow obstruction and resultant clotting and failure of the AV graft. (Paulson, W. D.; Ram, S. J.; Zibari, G. B., "Vascular Access: Anatomy, Examination, Management", Semin. Nephrol., Vol. 22, No. 3, May 2002, pp. 183-194). In AV fistulas, the common cause of failure is formation of venous aneurysms and clotting on the venous portion of the graft. Venous aneurysms are caused because of the flow pressure differential between the high pressure grafted artery and the vein. High pressure arterial flow through the thin walls of the veins causes damage because veins lack the prominent arterial layers of elastic and muscular tissue. These aneurysms then form clots because of the turbulent, irregular blood flow and subsequently the AV fistula completely clots off and fails. [U.S. Pat. Nos. 6,102,884; 6,086,553; 5,556,426; 4,822,341; 4,654,033; 4,479,798; 3,998.222; 3.826,257; 3,818,257; and 3,818,511—incorporated by reference.] Hemodialysis catheters are the least preferred in the surgical community. The large bore catheters can last from two months to one year and are frequently complicated by infection and clotting because the limbs of the catheters are outside of the skin.

It would be desirable to have an arteriovenous device placed subcutaneously that does not require anastomisis to a vein, eliminates exposure of the vein to high pressure blood returning to the patient from the dialysis apparatus and utilizes a single lumen venous outflow catheter. It would also be desirable to have an arteriovenous device that provides long term patency, prevents clotting and minimizes infection.

SUMMARY

The present invention provides an arteriovenous shunt comprising:

a. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis;

b. a single lumen venous outflow catheter comprising an intake end and depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart; and

c. a cuff comprising an inlet and an outlet, wherein:

i. said inlet is connected to said terminal end of said subcutaneous graft; and

ii. said outlet is connected to said intake end of said venous outflow catheter.

The present invention also provides a system for performing hemodialysis on a patient comprising:

a. an arteriovenous shunt comprising:

i. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis; and

ii. a single lumen venous outflow catheter comprising an intake end and a depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart; and

iii. a cuff comprising an inlet and an outlet, wherein:

1. said inlet is connected to said terminal end of said subcutaneous graft; and

2. said outlet is connected to said intake end of said venous outflow catheter; and

b. a hemodialysis apparatus.

The present invention additionally provides a method of performing hemodialysis on a patient comprising:

a. inserting an arteriovenous shunt into a patient, wherein said arteriovenous shunt comprises:

i. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis;

ii. a single lumen venous outflow catheter comprising an intake end and depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart; and

iii. a cuff comprising an inlet and an outlet, wherein:

1. said inlet is connected to said terminal end of said subcutaneous graft; and

2. said outlet is connected to said intake end of said venous outflow catheter;

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b. connecting said arterial graft to a hemodialysis apparatus;

c. collecting blood from the patient through said subcutaneous graft;

d. passing said blood through the hemodialysis apparatus;

e. collecting purified blood from hemodialysis apparatus; and

f. transmitting said purified blood through said cuff into said venous outflow catheter.

It has been found that the methods and apparatus of this invention afford benefits over methods and apparatus among those known in the art. Such benefits include one or more of long term patency, prevention of clotting and minimizing infection. Further benefits and embodiments of the present invention are apparent from the description set forth herein.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will become more fully understood from the detailed description and the accompanying drawings. wherein:

FIG. **1** depicts the segments of an arteriovenous shunt of the present invention.

FIG. **2** depicts an arteriovenous shunt of the present invention in an upper extremity.

FIG. **3** depicts an arteriovenous shunt of the present in a lower extremity.

It should be noted that the figures set forth herein are intended to exemplify the general characteristics of an apparatus, materials and methods among those of this invention, for the purpose of the description of such embodiments herein. These figures may not precisely reflect the characteristics of any given embodiment, and are not necessarily intended to define or limit specific embodiments within the scope of this invention.

DETAILED DESCRIPTION OF THE INVENTION

While this invention is susceptible of embodiments in many different forms, there are shown in the drawings and will herein be described in detail, preferred embodiments of the invention with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspect of the invention to the embodiments illustrated.

The present invention provides devices, systems and methods for subcutaneously positioning a graft and catheter for access to the vascular system of a patent.

The following definitions and non-limiting guidelines must be considered in reviewing the description of this invention set forth herein.

The headings (such as "Introduction" and "Summary,") and sub-headings (such as "Surgical Methods") used herein are intended only for general organization of topics within the disclosure of the invention, and are not intended to limit the disclosure of the invention or any aspect thereof. In particular, subject matter disclosed in the "Introduction" may include aspects of technology within the scope of the invention, and may not constitute a recitation of prior art. Subject matter disclosed in the "Summary" is not an exhaustive or complete disclosure of the entire scope of the invention or any embodiments thereof.

The citation of references herein does not constitute an admission that those references are prior art or have any relevance to the patentability of the invention disclosed herein. Any discussion of the content of references cited in the Introduction is intended merely to provide a general summary of assertions made by the authors of the references, and does not constitute an admission as to the accuracy of the content of such references. All references cited in the Description section of this specification are hereby incorporated by reference in their entirety.

The description and specific examples, while indicating the embodiment of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention. Moreover, recitation of multiple embodiments having stated features is not intended to exclude other embodiments having additional features, or other embodiments incorporating different combinations stated of the features.

As used herein, the words "preferred" and "preferably" refer to embodiments of the invention that afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the invention.

As used herein, the word "include" and its variants is intended to be non-limiting, such that recitation of items in a list is not to the exclusion of other like items that may also be useful in the materials, compositions, devices, and methods of this invention.

Materials

An embodiment of this invention consists of 3 parts. FIG. **1**. The first part is a flexible graft **11**. The graft **11** measures from about 2 to 8 mm in diameter. In a preferred embodiment, the diameter is about from 6 to 8 mm. In general, graft lengths range from 20 to 60 cm in length. Preferably, the graft is about 40 cm in length. The diameter and length of the graft depends on whether insertion is through an upper or lower extremity and the patient's body size. Agraft placed in the lower extremity will be longer than a graft placed in the upper extremity. For example, the graft dimensions in a child with a graft in the upper extremity will be of smaller dimensions than those in an adult with a graft in the lower extremity. The flexible material is biocompatible and does not substantially adversely affect the function, growth and any other desired characteristics of the tissue cells surrounding the implanted device. In a preferred embodiment, the graft is made of polytetrafluoroethylene (PTFE) or polyurethane (Vectra® Graft by Thoratec).

The second part consists of a single lumen venous outflow catheter **12**. The venous outflow catheter **12** has a smaller diameter than the PTFE graft **11**. In a most preferred embodiment, the catheter is 1 mm smaller in diameter than the graft. Venous outflow catheters have a diameter from about 1 to 7 mm. Preferably, the catheter diameter is 5 mm. The catheter diameter should be sufficient to allow for the proper fit of the catheter in the cuff **13**. Similar to the graft size, the catheter size will vary depending on the age and/or body size of the patient. The catheter length can range from 20 to about 80 cm. A preferred length is from about 40 to about 60 cm. The length of the catheter must be sufficient to advance through the vein into the right atrium. The catheter is polyurethane, silicone or other biocompatible materials can be used.

The single lumen venous outflow catheter is connected to the graft by surgical anastomosis over a cuff **13**. The cuff inlet is connected to the graft **11** terminal end and the cuff outlet is connected to the venous outflow catheter **12** inlet. In a preferred embodiment, the inside diameter of the cuff is graded to compensate for the size difference between the graft and the venous outflow catheter. The cuff is preferably Teflon® or Dacron®.

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The total length and various diameters of shunt components will vary depending on the size of the patient, the vein or artery used and the extremity length of the patient. The shunt **10** is placed under the skin-via strict sterile surgical technique and connected to the artery (brachial, axillary, femoral or external iliac) via careful anastomosis. The shunt can be used for extracorporeal vascular access **21** through the graft. For example, hemodialysis is performed by using dialysis cannulas temporarily placed into the graft in a sterile fashion.

Embodiments of this invention begin in the artery and have a final deposit site in the right atrium. In addition to being an arteriovenous shunt due to the path between the artery and vein, embodiments of this invention are "arterioatrial" due to the path created between the artery and the right atrium. The term "arterioatrial" is not limiting to the path or methods of creating a path, but is used as a supplemental explanation and description of embodiments of this invention. This connection eliminates the need for anastomosis to a vein and thus eliminates the frequent problems that exist when a high flow system transmits into a vein such as venous aneurysms in AV fistulas and neointimal hyperplasia in AV grafts.

Methods of Use

Surgical Methods

The surgical technique for these procedures is best suited for a vascular surgical text or journal. (Benedetii, E.; DeiPino, A; Cintron J., Duarle, B., "A New Method of Creating an Arteriovenous Graft Access", Am. /. Surg., Vol. 171, No. 3, March 1996, pp. 369-370.) It is understood that one skilled in the art would recognize modifications needed to surgical procedures depending on the dimensions of the graft and individual patient needs.

The arteriovenous shunt is inserted into the patient subcutaneously using open surgical methods. The PTFE graft is anastomosed to an artery and the cuff is attached to the terminal end of the graft. The intake end of the venous outflow catheter is attached to the Teflon or Dacron cuff. A vein is "cut down" and a glide wire is inserted into the vein. The length of the glide wire required to reach the right atrium is used to determine the appropriate length of the catheter. The catheter is passed over the glide wire through the vein into the right atrium. A purse string stitch is then used to close the opening of the vein around the catheter and prevent bleeding from the vein "cut down" site.

Purified Blood Flow in a Functioning Shunt

FIG. **2** demonstrates purified blood flow from an extracorporeal source **21**, such as a hemodialysis apparatus in embodiments of an arteriovenous shunt **10** functioning in the upper extremity. As depicted, the graft is anastomosed to the brachial artery **17**. The graft can also be anastomosed to the axillary artery. Blood flows from the high pressure brachial artery into the flexible graft of the shunt **10**. The graft is accessed by the dialysis cannula closest to the artery in the usual sterile fashion. The blood is then filtered through a dialysis machine, the toxins removed, and the purified blood is returned to the flexible graft via the other dialysis cannula closest to the cuff. The purified blood then flows via the venous outflow catheter through the cephalic vein **18** and deposits directly into the right atrium **14**. In another preferred embodiment, the catheter passes through the axillary vein. A key advantage of embodiments of this invention is the complete avoidance of stenosis which contributes to the 80% failure rate of various vascular access methods. The high pressure blood returning from the hemodialysis apparatus is guided directly into the right atrium and all vein wall contact is avoided.

FIG. **3** depicts purified blood flow in an embodiment of the shunt functioning in the lower extremity. The graft is anastomosed to the femoral artery. Blood flows from the high pressure femoral artery **20** into the graft portion of the shunt **10**. The graft is accessed in the usual sterile fashion, by the dialysis cannula closest to the artery. The blood is then filtered through the dialysis machine, the toxins removed, and the purified blood is returned to the graft via the other dialysis cannula closest to the cuff. The purified blood then flows via the venous outflow catheter through the femoral vein **19**. In addition to the femoral vein, external iliac vein is also preferred. Blood then flows into the inferior vena cava **16** and deposits directly into the right atrium **14**.

A key advantage of embodiments of this invention is the elimination of vein wall damage, including stenosis, which normally causes the high failure rate of various vascular access methods. The high pressure blood returning from the hemodialysis apparatus is guided directly into the right atrium and therefore venous contact with the reentering blood is avoided.

Methods of Performing Hemodialysis

Embodiments of this invention include methods of performing hemodialysis on a patient. Blood is removed from the patient through the subcutaneous graft and is passed through the hemodialysis apparatus for purification. Purified blood is collected from the hemodialysis apparatus and then transferred to the cuff and then to the venous outflow catheter. The purified blood is then transferred through the catheter which passes through the vein into the patient's right atrium. The high flow system controlled by the hemodialysis apparatus is maintained directly to the right atrium.

While specific embodiments have been illustrated and described, numerous modifications come to mind without significantly departing from the spirit of the invention and the scope of protection is limited by the scope of the accompanying claims.

What is claimed is:

1. An arteriovenous shunt comprising:

a. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis and has a first diameter; and

b. a single lumen venous outflow catheter comprising an intake end and depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart and has a second diameter different from said first diameter; and

c. a cuff comprising an inlet and an outlet, wherein:

i. said inlet is disposed about said terminal end of said subcutaneous graft; and

ii. said outlet is disposed about said intake end of said venous outflow catheter;

wherein the cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter.

2. The arteriovenous shunt of claim **1** wherein said subcutaneous graft is made of a biocompatible flexible material.

3. The arteriovenous shunt of claim **2**, wherein said biocompatible flexible material is epolytetrafluoroethylene (PTFE) or polyurethane.

4. The arteriovenous shunt of claim **1**, wherein said arterial graft has a diameter from about 2 mm to about 8 mm and a length from about 20 cm to about 60 cm.

5. The arteriovenous shunt of claim **4**, wherein said arterial graft has a diameter of from about 6 mm to about 8 mm and a length of about 40 cm.

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6. The arteriovenous shunt of claim 1, wherein said artery is the brachial, axillary, femoral or external iliac artery.

7. The arteriovenous shunt of claim 1, wherein said cuff comprises polyethylene terephthalate or polytetrafluoroethylene.

8. The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter from about 1 mm to about 7 mm and a length of from about 20 cm to about 80 cm.

9. The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter from about 5 mm to about 7 mm and a length of from about 40 cm to about 60 cm.

10. The arteriovenous shunt of claim 1, wherein said venous outflow catheter is made of polyure thane or silicone.

11. The arteriovenous shunt of claim 1, wherein said vein is the cephalic, axillary, jugular, femoral or external iliac vein.

12. The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter of about 1 mm smaller than the subcutaneous graft.

13. A system for performing hemodialysis on a patient comprising:

a. an arteriovenous shunt means comprising:

i. an arterial graft means comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis and has a first diameter; and

ii. a-single lumen venous outflow catheter means comprising an intake end and depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart and has a second diameter different from said first diameter; and

iii. a cuff means comprising an inlet and an outlet, wherein:

1. said cuff is disposed about said terminal end of said subcutaneous graft; and

2. said cuff is disposed about said intake end of said venous outflow catheter; and

3. wherein the cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter; and

b. a hemodialysis apparatus.

14. The system according to claim 13, wherein said venous outflow catheter means has a diameter of about 1 mm smaller than said graft means.

15. The system according to claim 13, wherein said artery is the brachial, axillary, femoral or external iliac artery.

16. The system according to claim 13, wherein said vein is the cephalic, axillary, jugular, femoral or external iliac vein.

17. A method of performing hemodialysis on a patient comprising:

a. inserting an arteriovenous shunt into a patient, wherein said arteriovenous shunt comprises:

i. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis wherein said arterial graft has a first diameter of about 2-8 mm and length about 20 cm to 60 cm; and

ii. a single lumen venous outflow catheter comprising an intake end and depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart wherein said venous outflow catheter has a second diameter of about 1-7 mm; and a length from about 20 cm to about 80 cm;

iii. a cuff comprising an inlet and an outlet, wherein:

1. said inlet is disposed about said terminal end of said subcutaneous graft; and

2. said outlet is disposed about said intake end of said venous outflow catheter;

3. wherein the cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter; and

b. connecting said arterial graft to a hemodialysis apparatus;

c. collecting blood from the patient through said subcutaneous graft;

d. passing said blood through the hemodialysis apparatus;

e. collecting purified blood from hemodialysis apparatus; and

f. transmitting said purified blood to the graft and then through said cuff into said venous outflow catheter to be deposited into the right atrium.

18. The method according to claim 17, wherein said venous outflow catheter has a diameter of about 1 mm smaller than said subcutaneous graft.

19. The method according to claim 17, wherein said artery is the brachial, axillary, or femoral, external iliac artery.

20. The method according to claim 17, wherein said vein is the axillary, jugular, femoral or external iliac vein.

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